[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development of a Topical Ointment Containing Immunostimulatory CpG Oligodeoxynucleotides (ODN) for Dermatological Wound Healing

AGENCY: National Institutes of Health, HHS

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Six Therapeutics Technologies Holdings Group. ("Six Therapeutics") located in New Jersey**.**

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: *** Rose. M. Freel, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center at (301)-624-8775 or E-mail:rose.freel@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 61/639,688, filed April 27, 2012 and entitled “Use of CPG oligonucleotides co-formulated with an antibiotic to accelerate wound healing” [HHS Reference No. E-294-2011/0-US-01];

PCT Patent Application PCT/US2013/034639, filed March 29, 2013 and entitled “Use of CPG oligonucleotides co-formulated with an antibiotic to accelerate wound healing” [HHS Reference No. E-294-2011/0-PCT-02];

Australian Patent No. 2013252785, filed March 29, 2013, issued August 24, 2017, and entitled “Use of CPG oligonucleotides co-formulated with an antibiotic to accelerate wound healing” [HHS Reference No. E-294-2011/0-AU-03];

Canadian Patent Application No. 2871490, filed March 29, 2013, and entitled “Use of CPG oligonucleotides co-formulated with an antibiotic to accelerate wound healing” [HHS Reference No. E-294-2011/0-CA-04];

US Patent No. 10,076,535, filed October 24, 2014, issued September 18, 2018, and entitled “Use of CPG oligonucleotides co-formulated with an antibiotic to accelerate wound healing” [HHS Reference No. E-294-2011/0-US-05]; and

US Patent No. 8,466,116, filed September 5, 2008, issued June 18, 2013, and entitled “Use Of CpG Oligodeoxynucleotides To Induce Epithelial Cell Growth” [HHS Reference No. E-328-2001/1-US-01].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to: “Topical ointment containing K-type CpG oligodeoxynucleotides that

activate Toll-like receptor 9 to induce angiogenesis and epithelial cell growth, alone or in combination with other agents, for dermatological wound healing."

This technology discloses the use of CpG oligodeoxynucleotides (ODNs) to accelerate wound healing. The E-294-2011/0, technology relates to an antibiotic composition containing the toll-like receptor-7 (TLR7) ligand (imidazoquinoline) and an immunostimulatory K ODN. There is evidence that this formulation may produce more rapid wound healing versus standard antibiotic formulations. Because standard antibiotics eliminate bacteria at a wound site, they also eliminate the molecular signals present in bacterial DNA that stimulate the immune system's wound healing processes. The ODN and imidazoquinoline act as artificial immune stimulants that mimic the bacterial signals to improve healing rates. The E-328-2001/1 technology relates to a method of inducing epithelial cell growth by administration of immunostimulatory ODNs. The stimulation of epithelial cell growth also promotes wound healing.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: October 15, 2020.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

[FR Doc. 2020-23385 Filed: 10/21/2020 8:45 am; Publication Date: 10/22/2020]